

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10
(fictitious names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

PLAINTIFF TRUTEK CORP'S RESPONSE TO DEFENDANT
BLUEWILLOW BIOLOGIC'S MOTION TO EXCLUDE EXPERT
REPORT AND TESTIMONY OF
ALEXEI ERMAKOV AND SHANE BURNS

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EXHIBITS

Exhibit A Screen shots of relevant pages showing the NanoBio Protect product on the website *www.bluewillow.com* as it existed on February 7, 2021. The website is the property of Defendant, BlueWillow Biologics, Inc.

Exhibit B Resume of Dr. Alexei Ermakov

Exhibit C Resume of Shane Burns

Declaration of Dr. Edward A. Lemmo

I. INTRODUCTION

This brief is a response to "Defendant/Counter Plaintiff BlueWillow Biologics, Inc.'s Motion to Exclude the Expert Reports and Testimony of Alexei Ermakov and Shane Burns," submitted as ECF 57 on March 15, 2023. On March 30, 2023, the Court ordered that the time for replying to motions to exclude expert witness testimony is to be extended by two weeks. Subsequently, on April 21, 2023, the Court ordered that Plaintiff's response to Defendants motions to exclude will be due by May 22, 2023.

In its motion document, Defendant/Counter Plaintiff BlueWillow Biologics, Inc. ("Defendant" or "BlueWillow"), moved the Court to "exclude the expert report and testimony" of Dr. Alexei Ermakov ("Ermakov" or "Dr. Ermakov") and Shane Burns ("Burns" or "Mr. Burns"). Dr. Ermakov and Mr. Burns were designated by Plaintiff, Trutek Corp. ("Plaintiff" or "Trutek"), as its experts merely to offer testimony regarding data obtained from their experiments to measure and compare surface electrostatic charges on substrates coated with Trutek's and BlueWillow's products. The relevance these measurements will be discussed *infra*.

The brief accompanying Defendant's motion cited four reasons for excluding the expert reports and testimony of Dr. Ermakov and Mr. Burns. According to Defendant:

1. "Ermakov and Burns failed to use *reliable, tested, and peer reviewed* methodologies."¹
2. "Ermakov and Burns did not (a) *use appropriate scientific rigor*."¹
3. "Ermakov and Burns failed to *verify the contents and integrity of their test samples*."
4. "Ermakov and Burns test methods and results are not directed at the *appropriate inquiry* or *probative* subject matter."

Accompanying Defendant's motion and brief were six exhibits (ECF 57-2 through 6). The first was an expert report (Ex. 1, ECF 57-2) by Defendant's expert, Dr. Mansoor M. Amiji ("Amiji" or "Dr. Amiji"). Defendant's brief relies on opinions stated by Dr. Amiji in his expert report. Also included were the expert reports of Ermakov (Ex. 2 - ECF 57-3) and Burns (Ex. 4 - ECF 57-5). Both expert reports were submitted to Defendants Counsel as part of the present lawsuit. Also included were the deposition transcripts of Ermakov (Ex. 3 - ECF 57-4) and Burns (Ex. 5 - ECF 57-6), the testimonies of which were both taken by Defendant. Finally, included as an exhibit was a report (Ex. 6 - ECF 57-7) by Mr. Burns describing similar (but not identical) experiments performed in 2019 and related to an entirely different matter with data obtained from measuring entirely different substances.

¹ Emphasis supplied.

II. FACTUAL BACKGROUND

Trutek is a corporation having principal offices and laboratories in Somerville, New Jersey. Trutek has an intellectual property portfolio comprising several patents and trademarks. Trutek's patented technology dates back to the 1990's regarding various methods and formulations that are to be applied in the vicinity of a person's nasal passages. Most of the patents concern preparations that create an electrostatic field that either attracts or repels harmful particles, and inhibits their inhalation into the user's respiratory system. Based upon its several patents, Trutek manufactures and sells products under several brand names including NasalGuard®.

The patent at issue in this matter is U.S. Patent No. 8,163,802 ("the '802 Patent"), issued on April 24, 2012 and assigned to Trutek. The claims at issue recite a method and formulation that inhibits infections in a person caused by inhaling harmful particles into his or her respiratory system. The disclosed and claimed formulations electrostatically attract harmful particles in the air, holds those particles in place, and deactivates them. The process can be colloquially referred to a catch, hold, and kill. To create the electrostatic field, the formulations all contain a cationic agent and a biocide. A cationic agent is an ingredient that produces a positive electrostatic charge. A biocide is an ingredient that kills or deactivates harmful living

organisms. In two of the asserted claims, both the cationic agent and biocide are cited as the chemical material, benzalkonium chloride.

Among the products marketed by Trutek are NasalGuard Airborne Particle Blocker (a gel manually applied to the nostrils) and NasalGuard Misting Spray (a nasal spray). Both of these products use the technology of the '802 Patent (among other Trutek patents). All of the applicable Trutek patents (including the '802 Patent) are marked on the packaging as required by statute. Virtually all NasalGuard products are sold online over the Internet. The principal marketing arm for these products is *amazon.com*. Studies have confirmed that the NasalGuard products are very effective in diminishing the incidence of diseases (*e.g.*, cold and flu) in individuals that use these products.

Critical to the efficacy of the NasalGuard products is their ability to produce an electrostatic field that attracts harmful airborne particles. The electrostatic field is created by an electrostatic charge of the product when applied to a surface. In its own laboratories, Trutek personnel regularly confirm that its products exhibit an appropriate surface electrostatic charge. They do so by measuring resistivity of substrates coated with the NasalGuard products and then calculating the value of the surface charge.

Sometime around the end of 2020, Ashok Wahi, formerly President of Trutek noticed a product named Nanobio Protect being sold on *amazon.com*. He discovered that the product was manufactured and marketed by BlueWillow. At the time, the BlueWillow website described the product, and **it appeared to Mr. Wahi from that description that this product infringed on the asserted claims of the '802 Patent.** Screen shots of the relevant BlueWillow website pages (as they existed on February 7, 2021) accompany this brief as Exhibit A. On its website, **BlueWillow admits** that NanoBio Protect is a **nasal solution**, comprised of nanodroplets, containing **benzalkonium chloride**, that **attract "germs," surrounds them, and deactivates them by "membrane disruption."**

Trutek personnel then purchased samples of NanoBio Protect, and experimented with them in their own laboratories. The objective of these experiments was to confirm that NanoBio Protect indeed possessed a surface electrostatic charge capable of attracting harmful particles as asserted on the website. They found that the samples exhibited an electrostatic charge using the same experimental techniques that they use regarding Trutek's own products.

In an effort to **confirm their own findings, Trutek personnel** prepared samples of its own products as well as of the NanoBio Protect.

They then brought the samples to Dr. Ermakov and Mr. Burns with the intention of them conducting **a blind study to confirm the findings made in Trutek's laboratory.** Ermakov and Burns had performed similar tests for Trutek in the past. Neither Ermakov nor Burns knew the identity of the samples being tested until after their tests were completed. **Both scientists confirmed that all products exhibited a surface electrostatic charge of the same order of magnitude.**

Neither the NasalGuard nor NanoBio products are pharmaceuticals. They are more like cosmetics. Their effectiveness is to prevent some harmful particles from entering the respiratory system, or if they do, most of them would be inert. The products are more like face masks, but they are chemical in nature. In actual use, the NasalGuard and NanoBio products are applied by individuals to their nasal areas very crudely. The NasalGuard gel is applied using one's fingers, the NasalGuard spray is applied using a spray bottle, and the NanoBio Protect product is applied using a swab. No care is taken to create a uniform dose. Thus, measurement of the surface charge with precision is unnecessary. It was only desired to obtain generally comparable data from the various products.

III. EXPERT QUALIFICATIONS

The threshold requirement of Fed. R. Evid. 702 is that an expert designated by a party to testify must establish that the witness is "qualified as an expert by knowledge, skill, experience, training, or education."

A. QUALIFICATIONS OF DR. ALEXEI ERMAKOV

Dr. Ermakov is qualified under all of the stated criteria. His resume accompanies this brief as Exhibit B.

Dr. Ermakov is an Associate Research Professor and Director of Chemistry Instruments & Experiments at Rutgers, the State University of New Jersey. He was educated in Russia, and he received his MS in Physics from Leningrad State University in 1984 and his Ph.D. from St. Petersburg State University in 1992. His research areas include development of new techniques and instrumentation for research in surface science, chemistry, and nanotechnology.

Dr. Ermakov joined Rutgers University in 1992 as a post-doctoral fellow. He became an Assistant Research Professor in 2000, and he assumed his present position as a Director in the Department of Chemistry in 2004.

Dr. Ermakov has published extensively. One of his publications is on the development of a contactless conductivity sensor. He is a co-inventor on

a patent for an apparatus for inductive measurements of conductance. Among his awards, in 2011, he received the R&D 100 Award for development of a novel autoresonant electrostatic ion trap mass spectrometer.

B. QUALIFICATIONS OF SHANE BURNS

Shane Burns has been an employee of Electro-Tech Systems ("ETS") located in Perkasio, Pennsylvania, since 2016. Although he does not possess an advanced degree, he holds the position of Test Laboratory Manager at ETS. He has numerous certifications of his expertise from the EOS/ESD Association, and he attained ESD Program Manager Certification in 2021. He is also certified by the WG11 ESD Packaging Committee on several ANSI/ESD standards. Since 2016, he oversaw ETS's inter-laboratory proficiency testing program including humidity, temperature, static delay, electrical capacitance, resistance, and voltage. He personally performed over 10,000 tests himself. He is intimately familiar with equipment and testing techniques to measure electrostatic charge using Faraday cups and coulombmeters.

IV. DAUBERT REQUIREMENTS

The court in *Daubert v. Merrell Dow Pharmaceuticals*, 43 F.3d 1311, 1315 (9th Cir. 1995) set forth a two-part test to determine admissibility of scientific expert testimony:

Part 1:

- *Whether expert's testimony reflects "scientific knowledge."*
- *Whether their findings are "derived by the scientific method."*
- *Whether their work product "amounts to good science."*

Part 2: (the "fit" requirement)

Whether proposed testimony is relevant to the task at hand, i.e., that it logically advances a material aspect of the proposing party's case.

Accompanying submission of this brief is the Declaration of Edward A. Lemmo, Ph.D. Dr. Lemmo is Trutek's designated expert, and he submitted four expert reports of his opinions (1) that the NanoBio Protect product infringes upon the asserted claims of the '802 Patent, and (2) rebutting Dr. Amiji's opinions on (a) non-infringement, (b) invalidity of the '802 Patent, and (c) claim construction of the '802 Patent. Clearly, Dr. Lemmo does not agree with many of Dr. Amiji's opinions. Dr. Lemmo's resume is attached to his Declaration as Exhibit 1.

Dr. Lemmo is very familiar with the '802 Patent and the NasalGuard products. He is also familiar with the technology and ingredients of the NanoBio Protect product. In his opening technical report alleging infringement of the '802 Patent by BlueWillow in June 2022, Dr. Lemmo

relied on Dr. Ermakov's and Mr. Burns' reports. When Defendant's expert, Amiji, criticized the Ermakov and Burns reports, Dr. Lemmo submitted a responsive expert report in rebuttal to Amiji's opinions.

Measurement of surface electrostatic charge is not new science. Many textbook methodologies exist for doing so. They existed since the mid-Nineteenth Century. Formulae for calculating surface electrostatic charge from measurements of associated properties (*e.g.*, conductivity, resistivity) are well known.

In October 2022, Dr. Lemmo visited Dr. Ermakov's and Mr. Burns' laboratories. He observed the apparatus used by each, and he saw a demonstration of how the equipment used by both Ermakov and Burns functions.

A. DR. ERMAKOV'S PROPOSED TESTIMONY

In his Declaration, Dr. Lemmo discusses his meeting with Dr. Ermakov and the initial development of his apparatus (Decl. Lemmo, ¶¶ 15-19), the description and operation of Ermakov's apparatus, including how electrostatic charge is determined (*Id.* at ¶¶ 20-22); and how Ermakov's apparatus was used for testing in the present lawsuit (*Id.* at ¶¶ 23-30).

Contrary to Defendant's allegation, Dr. Ermakov's apparatus and test methodology was not developed for the purposes of this lawsuit. Instead, it

was developed in 2019 for the purpose of measuring surface electrostatic charge. Although, it was used initially to provide data that was used in another lawsuit, the apparatus was used numerous times since 2019 to detect and to measure electrostatic charges of different materials including those manufactured by Trutek in different stages of development. Dr. Lemmo stated:

In his position at Rutgers University, Dr. Ermakov regularly designs instrumentation for chemical experimentation. Although Dr. Ermakov designed his apparatus to solve the specific problem of measuring the surface electrostatic charge of a chemical applied to a substrate independent of the substrate used, his solution to the problem followed logical principles. Its design and operation can be easily understood by virtually any undergraduate physics student. It is the natural solution to this type of problem. It is not rocket science. (Id. at ¶ 30.)

Thus, as required by *Daubert*, (1) Dr. Ermakov's testimony will reflect "scientific knowledge;" (2) his findings are "derived by the scientific method;" and (3) Dr. Ermakov's work product amounts to "good science." Regarding the second part of the *Daubert* test, the issue of whether the Nanobio Protect product exhibits an electrostatic charge is critical to the issue of infringement. Therefore, Dr. Ermakov's testimony is probative and advances a material aspect of Trutek's case.

B. SHANE BURNS' PROPOSED TESTIMONY

Dr. Lemmo visited Mr. Burns at ETS on October 17, 2022. In his Declaration, Dr. Lemmo describes the apparatus used by Mr. Burns to perform his testing. (*Id.* at ¶ 32.) He then discusses the test standard used by Burns in this instance. (*Id.* at ¶ 33.) Unlike the situation with Dr. Ermakov's more recently developed apparatus, Mr. Burns used the type of apparatus that was in standard use for more than a century. Dr. Lemmo then discussed the nature of the testing and the results obtained. (*Id.* at ¶¶ 34-36.) He pointed out that pigskin, which was used as the substrate for testing the products, is often used as a testing model for human skin. (*Id.* at ¶ 35.) Further, the pigskin substrates were frequently deionized and tested to ensure that they did not contribute to the electrostatic charge. Mr. Burns' methodology followed well accepted standards (*Id.* at ¶ 33), and his testing method and test data were reviewed by his supervisor (*Id.* at ¶ 31).

Thus, as required by *Daubert*, (1) Mr. Burns' testimony will reflect "scientific knowledge;" (2) his findings are "derived by the scientific method;" and (3) Mr. Burns' work product amounts to "good science." Regarding the second part of the *Daubert* test, the presence of an electrostatic charge on a substrate coated with the NanoBio product is germane to the issue of infringement. Therefore, Mr. Burns' testimony is probative and advances a material aspect of Trutek's case.

V. REBUTTAL TO DEFENDANT'S ARGUMENTS FOR EXCLUSION OF EXPERT REPORTS AND TESTIMONY

Defendants move to exclude both the expert reports and proposed testimony of Ermakov and Burns. Their request to exclude the expert reports is confusing. Typically, expert reports, although marked for identification, they are not admitted into evidence. Instead, they are provided to an expert witness at trial to refresh his or her recollections. In addition, they are often used to impeach expert witnesses when their trial testimony is inconsistent with the opinions stated in their reports. Thus the request to exclude the expert reports is puzzling and inappropriate, and the motion to do so should be denied.

As discussed *supra*, Defendant argued that Ermakov and Burns test methodologies were not peer reviewed. While this is true in Ermakov's case, it is not true for Burns' case. Burns followed well established published standards to testing his samples. Further, his methodology and results were reviewed by another disinterested party. As for Ermakov's testing methodology, peer review is not an absolute requirement as long as his methods and results are sound and logical. *Smelser v. Norfolk S. Ry.*, 105 F.3d 299, 303 (6th. Cir. 1997). Ermakov's instrument design and experimentation represent good science. *See* Decl. Lemmo.

To illustrate its point that Burns testing methodology is flawed, Defendant uploaded a similar report from Mr. Burns dated July 30, 2019. They pointed out that the measurement of electrostatic charge of Trutek's product taken at that time did not correlate to that made on January 18, 2021, and that the measurements were off by more than an order of magnitude. However, the 2019 and 2021 experiments measured different products. The NasalGuard Misting Spray did not exist in 2019. There was a change in the formulation to enable electrostatic action on ultra-fine particles. Defendant is comparing apples to oranges.

Defendants advance an argument that neither Ermakov nor Burns verified the identity and method of collection of the samples that they tested. This was done on purpose. It was intended that Dr. Ermakov and Mr. Burns conduct a blind test, and that the identity of the samples would be revealed to them solely for inclusion in their reports. The samples were prepared by Trutek personnel in vials that were labeled by them. Their methods of preparation and delivery will be elicited from the Trutek witnesses as fact testimony. These individuals played no part in the testing. They merely were observers.

Trutek's NasalGuard products and BlueWillow's NanoBio Protect product are not pharmaceuticals. Neither one acts inside the bloodstream or

respiratory system, but rather externally to inhibit inhalation of harmful particles into the lungs where they are more likely to infect an individual. They act more like a chemical face mask that electrostatically filters these particles. In his opening report on patent invalidity, Defense expert, Amiji, states his belief that Trutek's products are cosmetics, and that the Handbook of Cosmetic Science and Technology is relevant to formulating the products disclosed in the '802 Patent.²

The Trutek NasalGuard products are applied to the nasal area either with the user's fingers (in the case of a gel) or with a spray bottle. The BlueWillow NanoBio Protect product is applied using a swab. Because the method of application is crude and non-reproducible, precision in applying the product coatings to the test substrates would be meaningless. Moreover, regarding Defendant's allegation that the Ermakov and Burns tests do not match *in vivo* conditions, it would be extremely difficult to perform electrostatic field measurements on a living, breathing human subject. Studies have proven that Trutek's products are effective in reducing the risk of infection from cold and flu viruses, and NanoBio Protect has a similar effectiveness (*see* Exhibit A). Trutek normally performs quality control measurements of the surface charge of its products on paper substrates. The

² "Opening Expert Report of Mansoor M. Amiji, Ph.D. On Invalidity," Pg. 13, ¶ 28.

objective is to detect an electrostatic charge of its own products within an order of magnitude. When Trutek's personnel read BlueWillow's admission that NanoBio's positively charged nano droplets attracted "germs." and read on all the elements of the claims of the '802 Patent, Trutek's objective was to merely experimentally confirm the presence of an electrostatic field. It appears that Defendant's reason for excluding the testimony of Dr. Ermakov and Shane Burns is a desire to deny that its product exhibit an electrostatic charge. Based on BlueWillow's admissions, that cat is already out of the bag.

Defendants criticize Dr. Ermakov because:

his research never focused on: (1) techniques or instrumentation for measuring electrostatic surface charge of pharmaceutical formulations, (2) measuring electrostatic charge of water-in-oil nanoemulsions, (3) techniques or instrumentation for measuring electrostatic surface charge for pharmaceutical products that are intended to be applied to the human skin, or (4) techniques or instrumentation to measure the electrostatic surface charge of pharmaceutical products that function through electrostatic forces.

Defendant is focused on pharmaceuticals, whereas none of the products are pharmaceuticals. Further, Dr. Ermakov's expertise is in "development of new techniques for instrumentation for research in surface science, chemistry, and nanotechnology." (See Exhibit B - Ermakov Resume.) Dr. Ermakov is a physicist and a chemist. The apparatus that he

developed in 2019 is ubiquitous in being able to measure the surface charge of any chemical substance coated on any substrate that would fit in his apparatus.

Defendant argues that there is no industry standard for testing electrostatic charge of liquids. However, neither Dr. Ermakov nor Mr. Burns did so. They each measured the surface electrostatic charge of dry substrates that were coated with a product that was no longer liquid.

Defendant argues that neither Ermakov nor Burns used adequate experimental controls. Yet, both performed their experiments on uncoated substrates in an effort to establish a baseline. Mr. Burns deionized the pigskin samples several times prior to actual testing. What additional controls does Defendant require?

Defendant states that "Ermakov and Burns' never-used-before methodologies lack independent validation." Defendant alleges that Dr. Ermakov invented his apparatus for this case alone, and used it for that sole purpose. Defendant cited the case of *Mike's Train House v. Lionel, L.L.C.*, 472 F.3d 398, 407 (6th Cir. 2006) to justify excluding experts that invent their methodology for the case in which they plan to testify. However, Dr. Ermakov developed his apparatus in 2019 for the purpose of solving a specific problem. True, it was first referenced by Trutek in another lawsuit,

but the apparatus has since been used to measure the electrostatic charges produced by a number of products on the market, and also to measure the charges on Trutek products as formulation development progresses. His apparatus was not invented solely for this case, nor has Dr. Ermakov ever testified in any legal matter. Similarly, Burns used his testing methodology as early as 2019 according to well established standards using equipment of the type in use for more than a century, but which is now manufactured by ETS as well as by other vendors.

Dr. Lemmo intends to offer expert opinion testimony confirming that the Ermakov and Burns apparatuses and experimental methodology are based on sound and logical scientific principles. Clearly, Dr. Lemmo and Dr. Amiji do not agree on much. Both disagree on the work performed by Ermakov and Burns. Ermakov and Burns disagree with Amiji's conclusions. However, disagreement among experts in a patent infringement matter is common and does not constitute a reason for excluding the testimony of one in favor of another.

VI. CONCLUSION

Unquestionably, despite Defendant's allegations, based on their education, experience, and skills, both Dr. Ermakov and Mr. Burns are

qualified as scientists to serve as experts who are able to provide testimony on electrostatic charges.

Based on arguments presented *supra*, this Court should deny Defendant's motion to exclude the expert reports, which will not be admitted into evidence.

Defendant failed to put forth convincing arguments that "Ermakov and Burns failed to use reliable, tested, and peer reviewed methodologies," and that they did not "use appropriate scientific rigor." Further, given the admissions made by BlueWillow regarding its NanoBio Protect product having an electrostatic charge that attracts negatively charged "germs," experiments to verify BlueWillow's admissions are directed at the appropriate inquiry and probative subject matter.

Dr. Edward Lemmo reviewed the work of Dr. Ermakov and found it to be based on sound, logical science. He also reviewed the work of Mr. Burns, as did also a colleague of Mr. Burns. Mr. Burns followed well established standards that have been around for many years.

The only logical reason for Defendant seeking to exclude data from experiments confirming that NanoBio protect produced an electrostatic charge would be if it wanted to walk back from the admissions made on its website. Plaintiff's and Defendant's experts disagree on the issues presented

in Defendant's brief. However, that is no reason to favor one expert over the other without appropriate rigorous inquiry at trial.

Based on arguments presented *supra*, Plaintiff respectfully requests that this Court deny Defendant's motion to exclude the expert reports and testimonies of Dr. Alexei Ermakov and Mr. Shane Burns.

Dated: May 22, 2023

Respectfully submitted,

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Hon. F. Kay Behm

CERTIFICATE OF SERVICE

Undersigned hereby states that on May 22, 2023, the attorneys for Plaintiff caused the foregoing document to be served upon all counsel of record, via electronic service.



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